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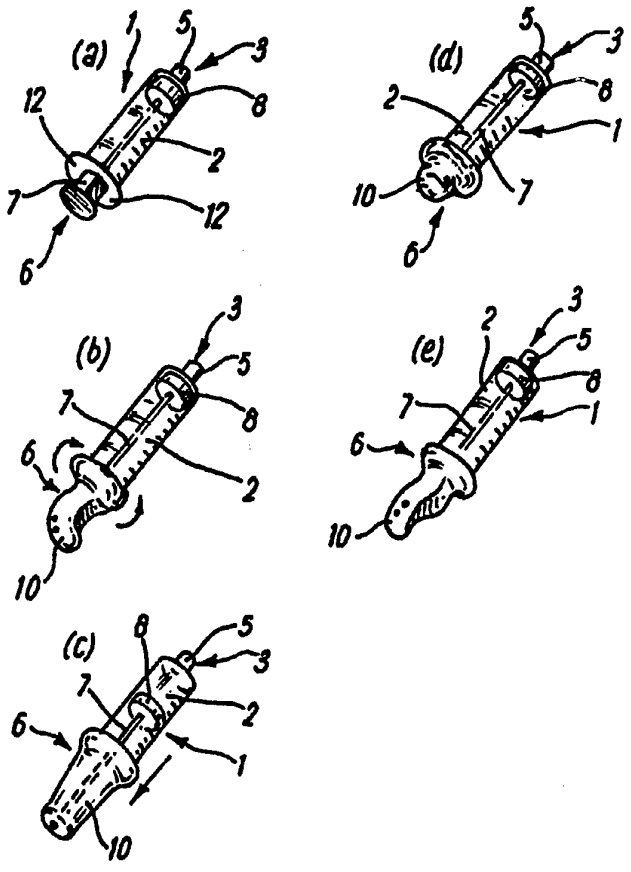
(54) Title: SYRINGE ASSEMBLY

(57) Abstract

A syringe assembly having a barrier at one end to prevent or diminish the entry of micro-organisms into the syringe barrel. The barrier can be in the form of an elastomeric bag or in the form of a rigid cover optionally with an elastomeric member such as an O-ring placed under pressure between the syringe and the cover. Alternatively the barrier can be in the form of a sleeve.



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SYRINGE ASSEMBLY

This invention relates to a syringe assembly which minimizes the risk of contamination of the interior of the syringe by micro-organisms from outside the syringe.

Syringes are commonly used to administer fluids such as drugs to patients. In some medical procedures it is desirable to administer drugs to a patient over a prolonged period of time using an intravenous conduit, one end of which remains in the patient, and the other end of which is attached to a syringe. It is also common procedure to use syringe pumps such as that disclosed in my previous International Application No PCT/GB87/00732. When the syringe is empty it is convenient to refill it by injecting fluid through a one-way valve positioned downstream of the outlet of the syringe.

Although these arrangements have been found to be satisfactory in many respects, the continued use of the same syringe means that when the syringe is emptied, the inner surface of the barrel of the syringe is exposed to the surrounding environment and can become

contaminated. Upon refilling of the syringe and movement of the plunger away from the outlet, some of the contaminated areas of the inner surface of the barrel can come into contact with the drug. This can result in eventual transfer of contamination to the patient.

According to the present invention there is provided a syringe assembly for the delivery of fluid, the assembly comprising a syringe having a barrel for containing fluid, the barrel having first and second ends, an outlet for fluid at the first end, and a piston movable along the inner surface of the barrel, characterised in that a barrier against passage of microorganisms is provided to resist contamination of the inner surface of the barrel between the piston and the second end of the barrel.

In one embodiment of the invention, the barrier comprises an elastomeric member. Additionally or alternatively, the barrier may include a non-elastomeric cover which extends over the second end of the barrel. The cover may substantially enclose the syringe leaving only the outlet protruding.

Advantageously the assembly is sterilised before use.

The barrier may be in the form of a tube having an elastomeric neck at one end which is disposed over, and forms a tight seal with, the second end of the barrel, and wherein the other end of the tube is sealed. Optionally the whole of the tube can be of elastomeric material. This tube can fit over the piston rod of a conventional syringe and the syringe can therefore be manually operated in a conventional manner by the user, or can be attached to a syringe pump such as that shown

in previous International Patent Application No PCT/GB87/00732.

The barrier can alternatively be in the form of a rigid cover which can extend over the second end of the barrel. This barrier can advantageously take the form of a syringe pump which can be sealed to the second end of the barrel, optionally by an elastomeric O-ring. The syringe pump can thereby seal off the inner surface of the barrel from the surrounding environment and diminish or prevent the transfer of contamination to the patient.

One form of syringe driving apparatus comprises a housing, a driving piston and a spring, each having first and second ends, the first end of said driving piston being located in said housing, the second end of said driving piston being extendable from the second end of said housing into the barrel, the first end of said spring acting on an abutment adjacent the first end of said housing and the second end of the spring acting on the driving piston.

When in use with the syringe assembly of the invention the above form of syringe driving apparatus can be used with a modified syringe which has a shortened piston (which may not have an axially extending piston rod) able to receive the driving piston of the syringe driving apparatus. An elastomeric tube can cover the driving piston as it extends into the barrel of the syringe thereby sealing off the inner surface of the barrel and the piston of the syringe from the surrounding environment.

Advantageously, the spring of the syringe driving apparatus is supported in the housing on an elongate

rod or spike.

In another embodiment of the invention, the barrier can be in the form of a sleeve (preferably sterile) disposed in the barrel and preferably secured to the piston of the syringe and spaced from the barrel. It is preferred that the sleeve in the assembly of this embodiment is spaced from the inner surface of the barrel by about 1-3mm. In such an assembly, any contaminating microorganisms present on the driving piston are prevented from transferring to the inner surface of the barrel by the sleeve and by the space between the sleeve and the barrel. It is further preferred that the driving piston is coaxial with and of a significantly smaller diameter than the sleeve, and that the driving piston engages the sleeve only at an end wall of the sleeve. Thus any contaminating microorganisms present on the driving piston are spaced from the side wall of the sleeve, and contamination is further reduced. In this embodiment an additional elastomeric seal can also be used if desired.

It is preferred that the barrier forms a fluid-tight seal with the syringe.

Embodiments of the present invention will now be described with reference to the accompanying drawings in which:

Fig. 1 shows a conventional syringe having a barrier in accordance with the invention;
Figs. 1a to 1e show the sequential steps of fitting the barrier on the syringe;
Fig. 2 shows a syringe assembly according to the invention for attachment to a syringe driving apparatus and a reservoir syringe;

Fig. 2a is an exploded view of the T-piece in the syringe assembly of Fig. 2;

Fig. 3 shows in cross section and in top view the connection arrangement between the syringe and the syringe driving apparatus shown in Fig. 2;

Fig. 4 is a cross section through the syringe driving apparatus shown in Figs. 2 and 3;

Fig. 5 is a cross section through a syringe assembly according to the invention connected to an alternative design of syringe driving apparatus;

Figs. 6 and 7 show syringe barrels with alternative designs of sleeve for use as a barrier in the present invention;

Fig. 8 is an exploded view of a piston and sleeve assembly for use in the present invention;

Fig. 9 shows a syringe having an alternative design of piston; and

Fig. 10 shows a patient-controlled drug delivery device having a drug reservoir with a barrier in accordance with the invention.

In accordance with the first embodiment of the invention described with reference to Figs. 1 to 3, a syringe assembly comprises a syringe 1 of conventional design having a barrel 2. The barrel 2 has a first end 3 with an outlet 5 and a second end 6 from which protrudes a piston rod 7. The piston rod 7 is attached to a piston 8 disposed in the barrel 2 of the syringe 1.

Over the syringe 1 at the second end 6 there is disposed a bag 10 of elastomeric material which forms the barrier. The bag 10 has one closed end and one open end at which is disposed an elastomeric neck 11. The elastomeric neck 11 extends over wings 12 of the

syringe 1.

The bag 10 prevents micro-organisms from passing from the environment surrounding the syringe into the syringe barrel 2 to contaminate the inner surface of the barrel 2.

The bag 10 can be used with the syringe 1 to provide a manually operated syringe assembly in which a user can apply pressure direct to the piston rod 7 with his/her thumb. The assembly of this embodiment of the invention can also be used in conjunction with syringe driving apparatus 15 such as is described in International Application PCT/GB87/00732. Where syringe driving apparatus 15 is used, the bag 10 can extend over the piston rod into the syringe driving apparatus 15 along with the piston rod 7 when the syringe 1 is full of fluid, thereby maintaining the barrier.

The syringe 1 can be filled with fluid from a reservoir syringe 20 which is connected to the syringe 1 via a T-piece 9 disposed downstream of the outlet 5. The reservoir syringe 20 typically has a one-way valve in the tubing connecting it to the T-piece such that upon emptying of the syringe 1 under pressure, the fluid does not re-enter the reservoir syringe 20 but is instead delivered to the patient. The tube conveying drug to the patient comprises a length of very narrow bore flow-control tubing 21 such as is described in PCT/GB87/00732. The flow-control tubing 21 is typically of a diameter between 50 microns and 254 microns, and is typically between 2 and 40 cms long.

When the syringe 1 is empty and is to be re-filled, fluid is forced from the reservoir syringe 20 through

the one-way valve and the T-piece 9. The resistance to flow into the syringe 1 is lower than the resistance to flow through the flow-control tubing 21. Thus the fluid flows preferentially into the syringe 1 and pushes the piston 8 along the barrel 2 of the syringe 1 towards the second end 6.

With reference to Figs. 5, 6, 7 and 8, a syringe assembly according to a second embodiment comprises a syringe 1 having a barrel 2 with a first end 3 having an outlet 5. In this embodiment, the syringe 1 has a shortened piston 8 (about 1cm) which has an axial indentation 16 in one face. The syringe piston 8 is attached to a sleeve 22 which has an axial protrusion 17 which fits into the axial indentation 16 on the syringe piston 8. Thus radial movement of the sleeve 22 relative to the syringe piston 8 is prevented.

The sleeve 22 can extend a short distance (eg 1 to 2 cms) along the barrel 2 as shown in Fig. 6 or can extend substantially the full length of the barrel 2 and protrude from the second end 6 thereof as shown in Fig. 7. The sleeve 22 is preferably sterile and can optionally be suitable for disposal after a single use.

The modified syringe of the second embodiment also optionally has an O-ring 25 disposed between the syringe driving apparatus and the second end 6 of the syringe 1. The connection between the syringe driving apparatus and the syringe can be by a bayonet fitting and is arranged so that the O-ring 25 is compressed between the syringe and the cover so as to form a fluid-tight seal at the junction between the two.

The syringe 1 of the second embodiment can be used in conjunction with an alternative design of syringe

driving apparatus 30. The syringe driving apparatus 30 comprises a housing 32, a driving piston 34, and a spring 35 disposed on an elongate spike 36. One end of the driving piston 34 is located inside the housing 32. The other end of the driving piston 34 is extendable from the end of the housing 32 into the barrel 2 of the syringe 1, and the spring 35 is disposed on the elongate spike 36 which extends part of the way into the driving piston 34. In an alternative embodiment the spring 35 and/or the spike 36 extends all the way into the driving piston 34 to an abutment (not shown) adjacent the end of the driving piston 34. The spring 35 is thus biased between the driving piston 34 and the housing 32 and exerts force on the driving piston 34 parallel to the axis of the syringe driving apparatus 30.

When connected to the modified syringe of the second embodiment, the syringe driving apparatus 30 transfers the force exerted by the spring 35 on the driving piston 34 to the syringe piston 8 as such that the syringe piston 8 is moved down the barrel towards the first end 3.

The driving piston 34 does not engage the syringe piston 8 directly but instead engages the sleeve 22, which forms the barrier between the inner surface of the barrel 2, preventing or diminishing transfer of microorganisms on the driving piston 34 onto the inner surface of the barrel 2 between the syringe plunger 8 and the second end 6. A second indentation in the inside surface of the sleeve 22 is arranged axially and cooperates with a second protrusion 19 on the driving piston 34 thereby to prevent the driving piston 34 from moving radially with respect to the sleeve 22.

The driving piston 34 is preferably slightly longer than the syringe barrel 2, and is preferably of a significantly smaller diameter than the sleeve 22. Typically in this embodiment, there is a gap of 1-3mm between the driving piston 34 and the sleeve 22, and between the sleeve 22 and the barrel 2.

The respective protrusions and indentations in the driving piston 34, sleeve 22 and syringe piston 8 keep them axially aligned with respect to each other, and thus keep the driving piston 34 and the sleeve 22 spaced from each other and the sleeve 22 spaced from the barrel 2. Thus transfer of contamination from the driving piston 34 is reduced.

The syringe 1 is connected to the syringe driving apparatus 30 by means of a bayonet fitting as shown in Fig. 3. The O-ring 25 is disposed between the respective ends of the housing 32 and the barrel 2 so as to form an fluid-tight seal. This also helps to reduce the risk of contamination.

A useful optional feature is the addition of a bacteria removing filter 29 in the fluid conduit to the patient, and/or at the second end 6 of the syringe as shown in Fig. 10. This provides a second barrier to the introduction of contaminating microorganisms to the patient. It is advantageous to provide a bacterial filter associated with a reservoir re-fill port to reduce the likelihood of contamination of the fluid in the reservoir.

Fig. 9 shows a syringe having a modified form of piston 40. The modified piston 40 is formed of elastomeric material and abuts the walls of the barrel 2 only at its tip 40a. The face 40b of the piston 40 has a

concave shape in contrast to conventional designs of pistons and the side walls 40c touch the walls of the barrel only at the tip 40a and the shoulder 40d, leaving a space 41 between the wall of the barrel to and the wall 40c of the piston 40. In one embodiment the side walls are concave also. This shape of piston minimizes friction between the piston 40 and walls of the syringe barrel 2 and maximises the accuracy of the delivery of fluid from the syringe 1.

Fig. 10 shows apparatus for patient-controlled supply of drugs from a demand syringe 43 actuated by the patient via a button 44. This arrangement is similar to the system described in International Patent Application No PCT/GB92/01184. The demand syringe 43 is filled from a reservoir syringe 45 which incorporates a barrier in accordance with the invention. The reservoir syringe 45 comprises a barrel 2 having a first end 3 with an outlet 5 and a second end 6, and a piston 8 which is moveable along the barrel 2.

The second end 6 of the syringe 45 has a barrier in the form of a cap 47 and bacterial filter 49 preventing contamination of the inner surface of the barrel 2.

In each embodiment of the invention described herein, the inner surface of the barrel at least between the syringe piston and the second end is sealed against contamination by micro-organisms. Thus, the syringe assembly according to the present invention can deliver a supply of fluid and be re-filled from a point downstream of the outlet without contamination of the fluid in the syringe by micro-organisms, since they will be prevented from contaminating the barrel.

All the features disclosed in this specification (including any accompanying Claims, abstract and drawings) may be combined in any combination, except combinations where at least some of such features are mutually exclusive.

Modifications and improvements may be incorporated without departing from the scope of the invention.

Claims:

1 A syringe assembly for the delivery of fluid to a patient, the assembly comprising a syringe having a barrel for containing fluid, the barrel having first and second ends, an outlet for fluid at the first end, and a piston movable along the inner surface of the barrel, characterised in that a barrier against passage of microorganisms is provided to resist contamination of the inner surface of the barrel between the piston and the second end of the barrel.

2 A syringe assembly as claimed in Claim 1, characterised in that the barrier comprises an elastomeric member.

3 A syringe assembly as claimed in Claim 1 or Claim 2, characterised in that the barrier comprises a cover which extends over the second end of the barrel.

4 A syringe assembly as claimed in any preceding Claim, characterised in that the barrier is in the form of a tube having an elastomeric neck at one end which is disposed over, and forms a tight seal with, the second end of the barrel, and wherein the other end of the tube is sealed.

5 A syringe assembly as claimed in any preceding Claim, wherein a piston rod extends from the piston and the barrier covers the piston rod.

6 A syringe assembly as claimed in any one of Claims 1 to 4, including a syringe driving apparatus, the syringe driving apparatus having a driving piston

which urges the piston of the syringe in a direction from the second end to the first end of the barrel.

7 A syringe assembly as claimed in Claim 6, characterised in that the barrier includes a sleeve which isolates the driving piston from the inner surface of the barrel.

8 A syringe assembly as claimed in Claim 6 or Claim 7, characterised in that the sleeve is spaced from the inner surface of the barrel.

9 A syringe assembly as claimed in any one of Claims 6 to 8, characterised in that the sleeve and the driving piston are maintained in co-axial relationship with the barrel.

10 A syringe assembly as claimed in any one of Claims 6 to 9, characterised in that a fluid-tight seal extends between the syringe driving apparatus and the syringe barrel.

11 A syringe assembly as claimed in any preceding Claim, characterised in that the barrier comprises a bacterial filter.

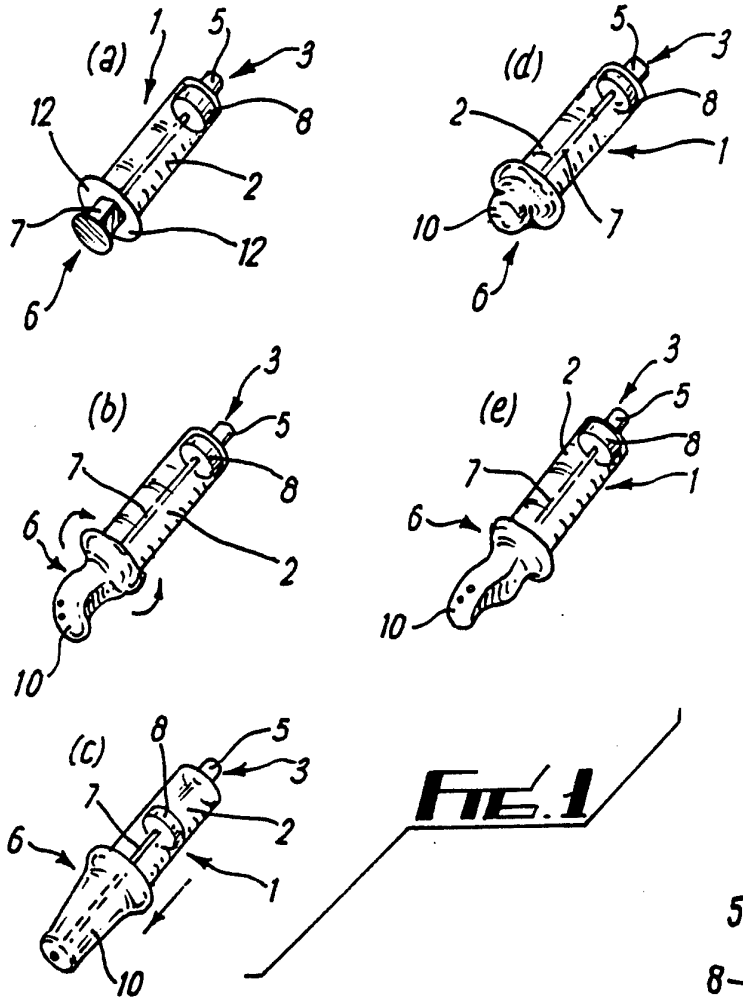


FIG. 1

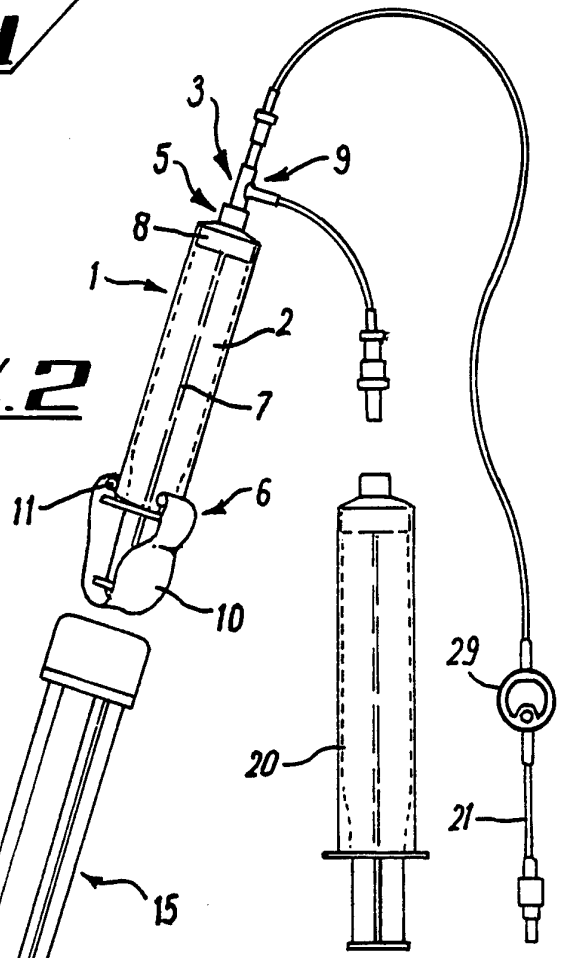


FIG. 2

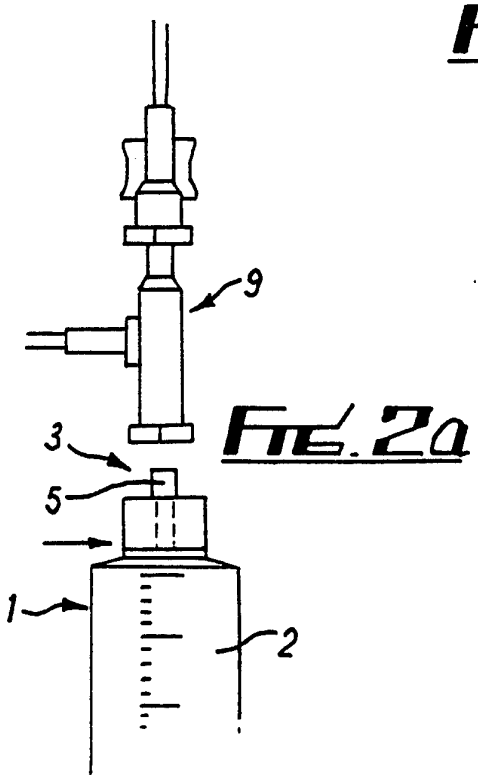


FIG. 2a

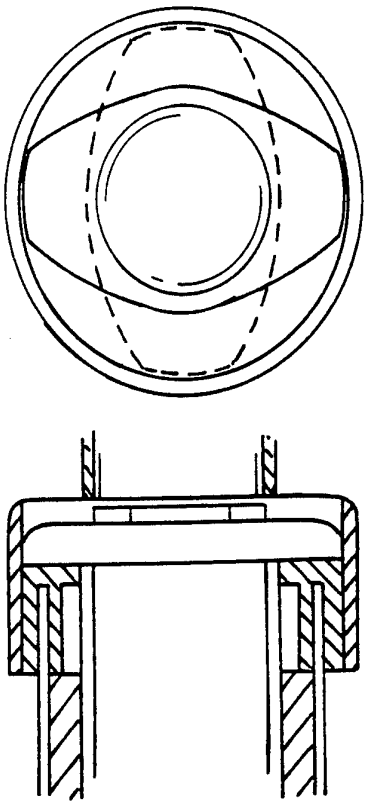


FIG. 3

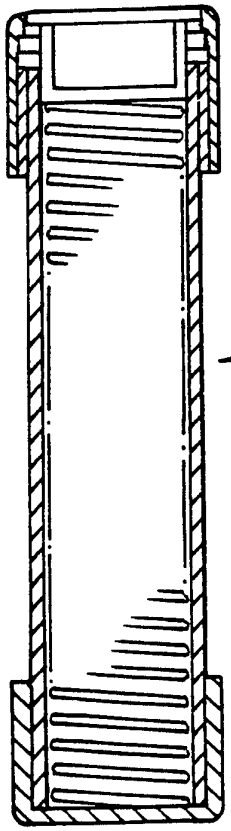


FIG. 4

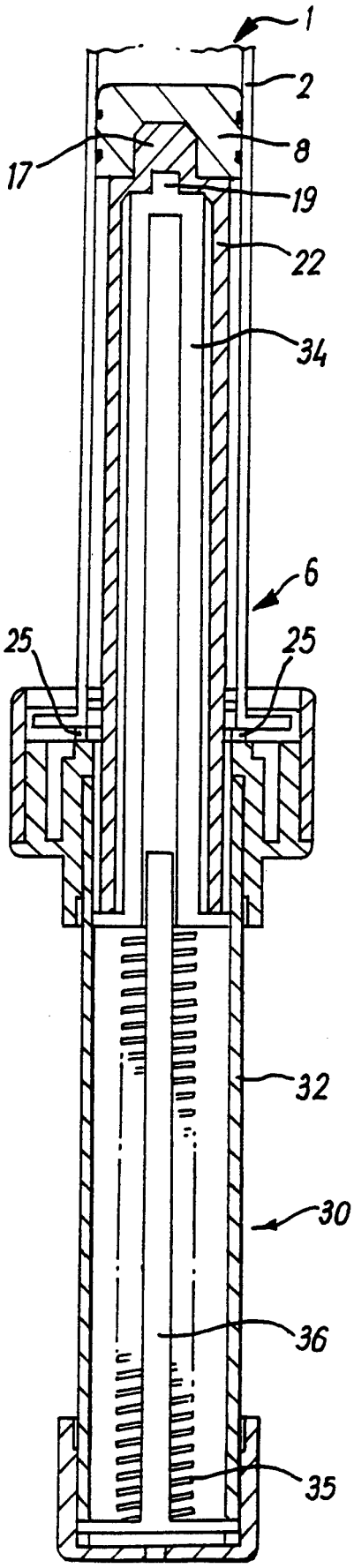


FIG. 5

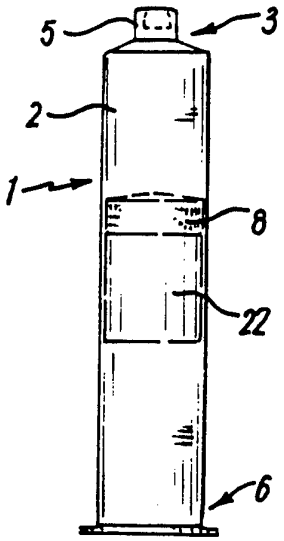


FIG. 6

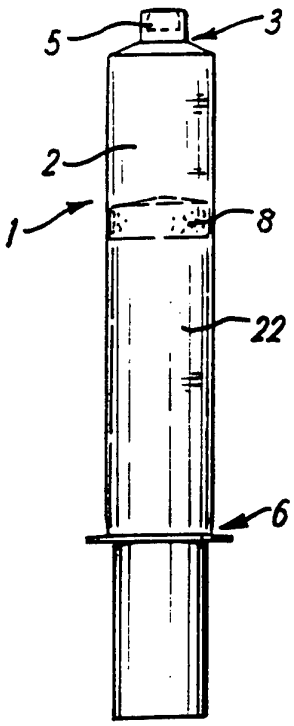


FIG. 7

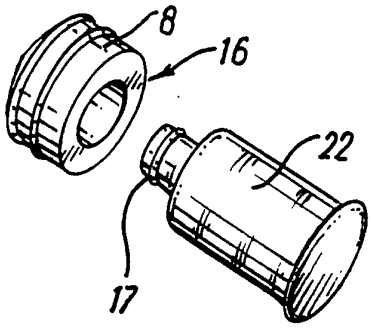
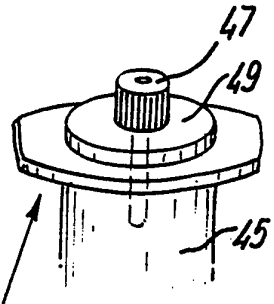


FIG. 8



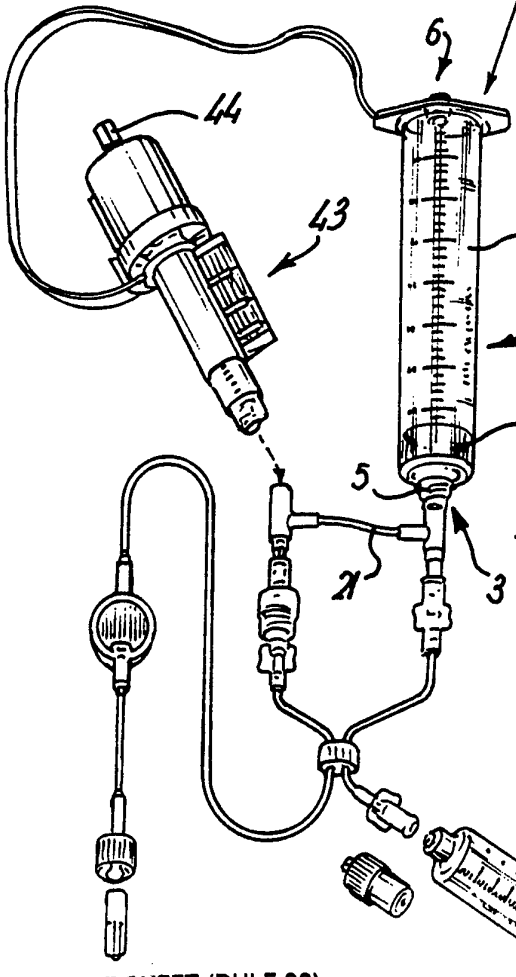
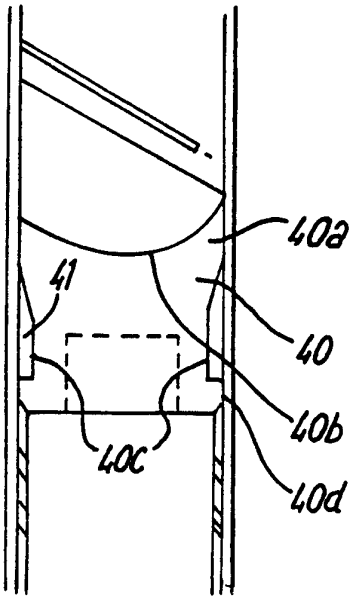


FIG. 10

FIG. 9



INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/GB 95/01117

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	WO,A,93 00944 (PATTULLO) 21 January 1993 see abstract; figure 1; examples 1,6	6-11
X	EP,A,0 376 603 (MEDEX INC) 4 July 1990 see column 2, line 44 - column 3, line 12; figure 1; examples 1-3	1-5
Y	WO,A,88 02637 (PATTULLO) 21 April 1988 see figures 11,12	6-10
A	US,A,5 265 621 (SIMPSON ET AL.) 30 November 1993	

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
28 August 1995	03. 10. 95

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Inter ɔnal Application No
PCT/GB 95/01117

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	US,A,5 332 092 (FISCHER) 26 July 1994	

1

INTERNATIONAL SEARCH REPORT

Inte: ɔnal Application No
PCT/GB 95/01117

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